Overview of the Medicare Prescription Drug Benefit
MMA Title I Summary

The Medicare Prescription Drug Benefit was established in Title I of the MMA bill on December 8, 2003.

Background

A. Medicare Prescription Drug, Improvement and Modernization Act of 2003

Title I of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) establishes a voluntary outpatient prescription drug benefit under a new Medicare part D that begins on January 1, 2006. Generally, coverage for the drug benefit will be provided by private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage plans that offer both prescription drug and health care coverage (known as MA-PD plans). Both types of plans must offer a standard drug benefit, but will have the flexibility to vary the drug benefit within actuarial equivalency parameters. Assistance with premiums and cost sharing are provided to eligible low-income beneficiaries. Covered part D drugs are essentially the same drugs and biologicals that are approved for the Medicaid program (although selection may be restricted through a plan's formulary) and they must be dispensed by prescription and on an outpatient basis.[1]

Medicare Drug Benefit

Standard Benefit

Beginning in 2006, Medicare beneficiaries will have access to the standard drug benefit described below. Although drug plan sponsors may change some of the specifications below, the benefit offered must at least be equal in value to the standard benefit. Standard coverage includes:

- A monthly premium of about $35
- A deductible of $250
- Coinsurance of 25 percent up to an initial coverage limit of $2250
- Protection against high out-of-pocket prescription drug costs, with co-pays of generally $2 for generics and preferred multiple source drugs and $5 for all other drugs, or 5 percent of the price, once an enrollee's out-of-pocket spending reaches a limit of $3,600

Low-Income Benefit

Those beneficiaries with limited savings and low incomes will receive a more generous benefit package, as described below:

Beneficiaries with limited savings and incomes below 135 percent of the federal poverty line ($12,123 for individuals, $16,362 for couples) will receive:

- A $0 deductible
- A $0 premium
- No gap in coverage

[1] Drugs and biological products that are paid by Medicare Part A or Part B are excluded.

- Co-pays of $2 for generics and preferred multiple source drugs and $5 for all other drugs, up to the out-of-pocket limit [NOTE: *For full dual eligibles under 100% of poverty, the co-payment is reduced to $1 and $3 and for those full dual eligibles who are residents of nursing homes there is no co-pay.]*
- $0 co-pay for all prescriptions once the out-of-pocket limit is reached.

Beneficiaries with limited savings and incomes below 150 percent of the federal poverty level ($13,470 for individuals; $18,180 for couples) will receive:

- A sliding scale monthly premium that would be about $35 for beneficiaries with incomes of 150 percent of the federal poverty level
- A $50 deductible
- No gap in coverage
- Coinsurance of 15 percent up to the out-of-pocket limit
- Copays of $2 or $5 once the out-of-pocket limit is reached

Alternative Prescription Drug Coverage Sponsoring organizations may offer coverage of part D benefits through plans that provide (1) the actuarial value of the total coverage that is at least equal to the actuarial value of standard prescription drug coverage, (2) access to negotiated prices, and (3) are approved by the Secretary.

Supplemental Prescription Drug Coverage PDPs and MA-PDs may provide supplemental prescription drug coverage consisting of cost-sharing reductions, and/or optional drugs. However, a PDP sponsor that offers a plan that provides supplemental prescription drug coverage must also offer a prescription drug plan in the area that only provides basic drug coverage. Basic coverage is either the standard benefit or the alternative prescription drug coverage.

B. Organizational Overview of Part 423

Section 101 of the MMA amended Title XVIII of the Social Security act by inserting a new Part D, which establishes the Medicare Prescription Drug Benefit.

Subpart A— General Provisions

- **Statutory basis**: Statutory basis for regulations.

- **Definitions:** Definitions include descriptions of actuarial equivalence and cost-sharing.

Subpart B— Eligibility, Election and Enrollment

- **Enrollment Periods for Part D:** Section 1860D-(1)(b) (1)(B) (iii) directs CMS to establish 3 coverage enrollment periods for Part D: the initial enrollment period, the annual coordinated election period and special enrollment periods.

- **Automatic enrollment of full-benefit dual eligible beneficiaries in part D plans:** Section 1860D-1(b)(1)(C) of the Act directs CMS to establish a process to automatically enroll, on a random basis where possible, full-benefit dual eligible beneficiaries who have not enrolled in a PDP or MA-PD plan into a prescription drug plan that has a monthly beneficiary premium that does not exceed the low income benchmark premium.

- **Late Fee:** As established under section 1860D-13(b) of the Act, a part D eligible individual is subject to a late enrollment penalty, in the form of increased premiums, if s/he fails to maintain creditable prescription drug coverage for a period of 63 days or longer.

Subpart C— Benefits and Beneficiary Protections

- **Requirements for prescription drug coverage:** Establishes requirements for qualified prescription drug coverage to be offered by PDP sponsors and MA-PD plans.

- **Prescription drug service areas:** Establishes requirements for prescription drug service areas.

- **Pharmacy networks:** Establishes minimum standards for the creation of prescription drug plan and MA-PD plan pharmacy networks. The purpose of these standards, which are equivalent to those used under the TRICARE Retail Pharmacy program, is to assure that enrollees have access to a sufficient number of pharmacies dispensing covered Part D drugs directly to them.

- **Formulary development:** Establishes requirements for formulary development for those prescription drug plans and MA-PD plans that plan to use a formulary.

- **Beneficiary protection requirements:** Establishes beneficiary protection requirements regarding the dissemination of Part D information to enrollees and prospective enrollees by PDP sponsors and MA organizations. Such information dissemination by plans will facilitate informed decisions by Part D eligible individuals about their Part D coverage options.

- **TROOP:** - True out-of-pocket costs. Beneficiary "costs" for drugs count towards the deductible and "donut-hole" only when they are paid by the beneficiary, a family member or an SPAP. Will be difficult to track.

Subpart D— Cost and Utilization Management, Quality Improvement, and Medication Therapy Management

- **Quality and management programs:** The major section of this subpart deals with quality assurance, drug utilization management, and medication therapy management programs. The regulations require that all PDPs or MA-PD plans,

except PFFS plans, to have such programs. These are designed to reduce medication errors and adverse drug events. Quality assurance measures, such as drug utilization review, are population-based, while medication therapy management optimizes therapeutic outcomes through pharmacists working with individual patients.

- **Consumer satisfaction surveys and accreditation:** Other provisions of this subpart deal with consumer satisfaction surveys for PDPs and deeming of accreditation organizations.

- **Electronic Prescription Standards:** PDP sponsors and MA Organizations offering MA-PD plans will need to support final e-prescribing standards once final standards are effective. These standards will be issued through a separate rulemaking.

Subpart F— Submission Of Bids, Premiums And Related Information And Plan Approval

- **Risk bids:** CMS will not accept risk bids from entities bidding or offering fallback plans in most cases.

- **Bid submission:** Bid submission process and rules are synchronized with Medicare Advantage.

- **CMS authority to review and negotiate bids:** CMS has authority similar to OPM to review and negotiate bids. We would interpret the non-interference provision as prohibiting CMS from setting the price of any particular drug or from requiring an average discount in the aggregate on any group of drugs, but allowing justification of aggregate price levels. Although CMS could not negotiate regarding the price levels of drugs, it could negotiate regarding the level of the overall bid and could exercise its authority to deny a bid if it does not believe that the bid and its underlying drugs prices reflect appropriate market rates.

- **Enrollee premiums:** Enrollee premiums are based on a national percentage of the national average monthly bid amount with adjustments up or down depending on the competitive standing of the plan bid relative to this national average.

- **Private fee-for-service (PFFS) and fallback plans:** Special rules for plans offered by private fee-for-service (PFFS) and fallback plans dictate different bidding, negotiation and approval processes.

Subpart G— Payments To PDP And MA-PD Plans

- **Monthly "direct subsidy":** PDPs and MA-PD plans receive a monthly "direct subsidy" equal to their bid amount, risk-adjusted for enrollee health status and minus the enrollee premium.

- **New prospective risk adjustment model:** The risk adjustment requires development of a new prospective risk adjustment model based on the relationship of drug usage to medical diagnoses. CMS will tie medical claims from MA and FFS beneficiaries to determine the Part D risk scores.

- **Monthly interim payments:** Monthly interim payments will be made on estimated reinsurance subsidies based on projections received and negotiated with the bids.

- **Monthly low-income subsidy payments:** Monthly low-income subsidy payments will be made based on 1) enrollee premiums and 2) estimated cost sharing subsidies based on projections received and negotiated with the bids (see Subpart P).

- **Risk sharing arrangements:** Risk sharing arrangements based on allowable costs (net of all price concessions) in specified symmetrical risk corridors will be calculated and paid (or recovered) following the end of the coverage year.

- **Reconciliation processes:** Extensive reconciliation processes will be required to settle prepaid to actual enrollment, risk adjustment, low-income subsidy, and reinsurance payments (in that order) prior to calculation of risk sharing.

Subpart I—Organization Compliance with State Law and Preemption By Federal Law

- **State licensure:** PDPs must be state licensed as risk-bearing entities.

- **Unlicensed PDPs:** Unlicensed PDPs may obtain a federal waiver based on certain criteria:

    1. State failed to act on application on a timely basis
    2. State licensure was denied based upon discriminatory treatment
    3. State denial based upon solvency standards higher than state licensure for other risk-bearing entities

- **Federal solvency standards:** Federal solvency standards for non-licensed entities to be developed by January 1, 2005 after consultation with the National Association of Insurance Commissioners.

Subpart J—Coordination with Plans and Programs that Offer Prescription Drug Coverage

- **SPAPs**: - State Pharmaceutical Assistance Programs. Unlike Medigap and all other insurers, SPAPs can wrap around the Part D benefits and have their payments or reimbursements of enrollee cost sharing count toward the Troop. We will provide "seed" money to facilitate coordination of SPAP programs and data with MA-PDs and PDPs - $62.5 million/year for 2005 and 2006.

- **"Qualified" MA-PRESCRIPTION DRUG:** All MA organizations offering coordinated care plans must offer at least one "qualified" MA-PD in all areas served.

- **Employer waivers:** Employer waivers under 1857(i) are extended to Part D for both MA-PDs and PDPs.

Subpart K— Application Procedures and Contracts with PDP Sponsors

- **Application process:** Description of process to apply and gain approval for a contract as a PDP sponsor

- **Terms of the contract:** The terms of the contract including: conditions necessary to contract as a PDP sponsor, contract provisions, effective date and term of contract

- **Requirements in contracts:** Requirements for provisions that must be included in PDP sponsor contracts with other entities.

- **Termination of the contract:** Instructions for non-renewal of contract or termination of the contract by CMS or the PDP sponsor.

Subpart L— Effects of Change of Ownership or Leasing of Facilities

- **Change of ownership:** Description of what constitutes change of ownership with or without novation agreement.

- **Effect of changing ownership:** Effect of changing ownership on the PDP sponsor's contract with CMS.

- **Leasing facilities:** Description of effect of leasing all or part of its facilities to another entity on the PDP sponsor's contract with CMS.

Subpart M— Grievances, Coverage Determinations and Appeals

- **Procedures:** Proposed subpart M establishes the procedures that Prescription Drug Plan (PDP) sponsors must follow for grievances, coverage determinations, exceptions to tiered cost-sharing formulary structures, exceptions for coverage of non-formulary drugs, redeterminations, reconsiderations, and appeals.

- **Similar to the Medicare Advantage (MA) program:** In general, the procedures governing grievances, coverage determinations, redeterminations, reconsiderations, and appeals are the same as those that apply to the Medicare Advantage (MA) program, except unfavorable redeterminations are not automatically forwarded to the independent review entity for reconsideration.

- **Exception procedures:** The new statute provides very little direction regarding the required procedures for obtaining exceptions to tiered cost-sharing rules, or obtaining coverage for a Part D drug that is not on a PDP's formulary. Our proposed approach is to establish general criteria for a PDP sponsor's exception procedures, but allow PDPs a great deal of flexibility to design specific criteria suitable to their particular formulary. Key required elements of a PDP's exceptions criteria include the following:

    - Must address both mid-year and annual formulary changes, as well as both existing use and new prescription situations. In existing use cases, provide for continued coverage of a drug that is the subject of an exceptions request for up to 1 month or until a determination is made, whichever is shorter, when a PDP sponsor fails to make a timely decision regarding an exceptions request.
    - Must consider cost difference between preferred and non-preferred drugs.
    - Must consider whether a requested drug is the therapeutic equivalent of another drug on the formulary.
    - Must spell out the process used to compare the safety and effectiveness of a requested non-formulary drug with that of an applicable formulary drug.
    - Must describe the cost-sharing implications when coverage is provided for a non-formulary drug.

Subpart N— Medicare Contract Determinations and Appeals

- **Procedures:** Description of procedures for making and reviewing the determination that an entity is not qualified to enter into a PDP sponsor contract, the determination to terminate a PDP sponsor's contract or a determination not to renew a PDP sponsors

- **Reconsideration:** Reconsideration applicability, rights and determinations.

- **Hearings:** Rights and process for hearing.

Subpart O— Intermediate Sanctions

- **Sanctions:** Types of sanctions, basis and procedures for imposing sanctions.

- **Civil money penalties:** Maximum amount of civil money penalties imposed by CMS.

Subpart P— Premiums and Cost-Sharing Subsidies for Low-Income Individuals

- **Eligibility for subsidy**: Eligibility for subsidy is based on income and resources**.** Eligible individuals must reside in one of the 50 states, have income below 150 percent of the FPL, and meet a resources/assets test. Individuals are divided into different groups, based on the amount of their income and resources, and are entitled to different amounts of subsidy assistance.

- **Eligibility determinations:** Eligibility determinations are made under the state Medicaid plan for states or by the Commissioner of Social Security. Eligibility determinations are effective with the first day of the month in which the individual applies for the subsidy and meets the eligibility requirements.

- **Amount of Subsidy:** The amount of the premium and cost-sharing subsidy varies depending upon the individual's income and resources/assets level.

- **Administration of Subsidy:** In order to administer these subsidies, CMS will notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy. The PDP sponsor or MA organization will then notify CMS that premiums or cost sharing have been reduced and the amount of the reduction. CMS will reimburse the sponsor or organization for the amount of the premium or cost-sharing reductions as provided in Subpart G.

Subpart Q— Fallback Plans

- **Bid submission:** Fallback plans would submit bids (proposals) pursuant to a separate contracting process in accordance with federal acquisition rules. This process would precede the risk bid process.

- **Bid review:** In reviewing and negotiating fallback bids, CMS would interpret the non-interference provision as prohibiting CMS from setting the price of any particular drug or from requiring an average discount in the aggregate on any group of drugs, but allowing both justification of aggregate price levels and negotiations around targeted price levels for categories of drugs as reference points for performance-based contracting with fallback plans.

- **Fallback plan availability:** Fallback plans would be offered in any region, or local area of any region, in which there was not a choice of at least two qualifying plans, one of which being a stand-alone PDP. An MA-PD may only be counted as qualifying if it is open to enrollment and not operating under a capacity waiver.

- **Premiums:** Premiums for enrollees in fallback plans will be collected by SSA or CMS.

- **Same terms and conditions as PDPs:** Fallback plans will be subject to the contract terms and conditions applicable to PDPs with the exceptions of contract term, marketing restrictions and performance-based payment.

Subpart S— Special Rules for States-Eligibility Determinations for Low-Income Subsidies

- **State requirements:** Specifies the requirements for States relating to low-income subsidies under Part D. States make available & assist with low-income subsidy applications, make initial eligibility determinations and redeterminations for premium and cost-sharing subsidies, screen for Medicare cost-sharing and enrollment under the State plan, and notify CMS of low-income subsidy eligibility determinations and redeterminations.

- **Medicare primary payer:** Specifies that, for persons eligible for Part D, medical assistance is not available for Medicaid covered drugs that could be covered under Part D. Medicare is the primary payer.

- **Grant funds for medical assistance:** Specifies the requirements for the Territories to submit plans to receive grant funds for medical assistance provided to low-income individuals for covered Part D drugs.

- **State monthly contribution:** Includes provisions for calculating the State monthly contribution to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals.

Subpart T— PACE organizations offering Part D coverage

- **Prohibition on Medigap policies:** Sales of Medigap policies with drug coverage (Plan H, I and J) are prohibited as of January 1, 2006.

- **Impact on PACE:** outlines the way in which the Part D prescription drug benefit will impact PACE organizations and provides guidance for implementing the MMA Part D prescription drug benefit. PACE was originally established as a permanent Medicare benefit and Medicaid State plan option under the Balanced Budget Act and has provided comprehensive prescription drug coverage to all enrollees.

- **Coordination of benefits:** The MMA specified that PACE organizations that provide Part D coverage shall be treated in a *similar* manner to MA-PD local plans. The legislation also allows the Secretary to waive provisions that duplicate or conflict with provisions otherwise applicable to plans or as may be necessary to improve the coordination with the benefits under the MMA.

- **Waiver of Part D provisions:** CMS has identified key areas where waivers of specific Part D provisions will be necessary to allow for a smooth transition in coordinating the Part D benefit with the PACE statute and regulations.